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No. 87-498

IN THE
Supreme Court of the United States
OCTOBER TERM, 1987

KEVAN BERKOVITZ, *et al.*,
Petitioners,

v.

UNITED STATES OF AMERICA,
Respondent.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Third Circuit

MOTION FOR LEAVE TO FILE BRIEF AS AMICUS CURIAE AND BRIEF FOR LEDERLE LABORATORIES, A DIVISION OF AMERICAN CYANAMID CO. AS AMICUS CURIAE IN SUPPORT OF RESPONDENT

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MOTION ON BEHALF OF LEDERLE LABORATORIES FOR LEAVE TO FILE BRIEF AS AMICUS CURIAE IN SUPPORT OF RESPONDENT

Lederle Laboratories, a division of American Cyanamid Co., moves for leave to file a brief as amicus curiae in support of respondent, United States of America. The respondent has consented to the filing of this brief, and the petitioners have denied consent.

Lederle Laboratories is the manufacturer of Orimune®, the polio vaccine alleged to have been administered to petitioner Kevan Berkovitz. Petitioners' claims against Lederle Laboratories have been settled. However, the

legal standards governing tort liability in suits challenging the design and licensing of vaccines are of keen interest to Lederle Laboratories in its continuing efforts to make safe and effective vaccines available to the public at a reasonable price.

The Third Circuit in its opinion below stated that it is the vaccine manufacturer who has the primary responsibility for insuring compliance with the applicable FDA regulations. *Berkovitz v. United States*, No. 86-3444, slip op. at 23 (3d Cir. June 30, 1986). The purpose of Lederle's amicus brief is to inform the Court of some of the issues surrounding manufacturer's liability that are currently working their way through the lower federal courts, and to advise against the adoption of any such broad language that might unnecessarily prejudice the outcome of these cases.

Respectfully submitted,

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BRIEF FOR LEDERLE LABORATORIES, A DIVISION OF AMERICAN CYANAMID CO. AS AMICUS CURIAE IN SUPPORT OF RESPONDENT

This amicus curiae brief is submitted in support of respondent United States of America. By letter filed with the Clerk of the Court, the respondent has consented to the filing of this brief. However, petitioners have denied consent, and a motion for leave to file accompanies this brief.

INTEREST OF AMICUS CURIAE

Lederle Laboratories is the manufacturer of Orimune®, the polio vaccine alleged to have been administered to petitioner Kevan Berkovitz. Petitioners' claims against Lederle Laboratories have been settled. However, the

legal standards governing tort liability in suits challenging the design and licensing of vaccines are of keen interest to Lederle Laboratories in its continuing efforts to make safe and effective vaccines available to the public at a reasonable price.

ARGUMENT

I. THE STANDARDS GOVERNING A MANUFACTURER'S TORT LIABILITY FOR "REGULATORY NONCOMPLIANCE" RAISE COMPLEX QUESTIONS THAT ARE NOT DIRECTLY PRESENTED BY THIS CASE AND THAT SHOULD BE EXPLICITLY RESERVED FOR FUTURE DECISION.

Both the Third Circuit in its opinion below and the government in some of its briefs have suggested that it is the vaccine manufacturer, rather than the government, who is primarily responsible for insuring compliance with federal vaccine regulations.[1] In fact, the responsibility is a shared one. Each batch of vaccine must be inspected both by the manufacturer and by the government before the manufacturer can release it for use, and the government's decision is final.

Petitioners have attempted to portray the vaccine licensing regulations at issue in this case as setting compliance standards that are completely objective and mandatory. That portrayal is not correct. The actual process of selecting and licensing particular biological products (such as vaccines) is a highly discretionary exercise involving subjective evaluations of complicated scientific evidence. Neither the government nor the manufacturer should be subjected to tort judgments based on an after-the-fact second-guess of such complex evaluations.

Petitioners in this case suggest that the government made no subjective judgments when it decided to license Lederle's original virus strains:

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[1] *See, e.g., Berkovitz v. United States*, No. 86-3444, slip op. at 23 (3d Cir. June 30, 1986); Brief for Appellant at 34-35, *Berkovitz v. United States*, No. 86-3444 (3d Cir. June 30, 1986).

> No policy judgment is needed, for example, to determine whether two paralyzed Macaca monkeys is a greater number than none; whether three lesions are more than two; whether a lesion which advanced 2 cm beyond the point of inoculation has a greater spread than one which advanced .5 cm from the inoculation site.

Petitioners' Brief at 16. But petitioners misconstrue the regulations upon which these examples are based. The relevant regulation, 42 C.F.R. § 73.114(b)(1)(iii) [1961], provides:

> *Determination of neurovirulence.* At the conclusion of the observation period comparative histopathological examinations shall be made . . . of each monkey in the groups injected with virus under test and those injected with the NIH Reference Attenuated poliovirus . . . . A comparative evaluation shall be made of the evidence of neurovirulence of the virus under test and the NIH Reference Attenuated Poliovirus with respect to (a) the number of animals showing lesions characteristic of poliovirus infection, (b) the number of animals showing lesions other than those characteristic of poliovirus infection, (c) the severity of the lesions, (d) the degree of dissemination of the lesions, and (e) the rate of occurrence of paralysis not attributable to the mechanical injury resulting from inoculation trauma. The virus pool under test is satisfactory for poliovirus vaccine manufacture only if at least 80 percent of the animals in each group survive the observation period and if a comparative analysis of the test results demonstrate that the neurovirulence of the test virus pool does not exceed that of the NIH Reference Attenuated Poliovirus.

These regulations do not involve objective tests that can be "passed" or "failed." Questions of the "severity" of the lesions under subpart (c) and whether particular lesions are "characteristic of poliovirus" under subparts (a) and (b), for example, involve complex scientific de-

terminations. The reviewer must engage in a subjective weighing of the available data, and must arrive at an overall conclusion as to whether the virus strain that was tested was more neurovirulent than the government's reference strain. The question of whether "a comparative analysis of the test results demonstrate that the neurovirulence of the test virus pool does not exceed that of the [government's reference strain]" is not an "objective" determination without room for discretion.

Vaccine manufacturers, as they must, rely on the government's interpretation of the requirements imposed by regulations like this one. The question whether a vaccine manufacturer should be subject to potentially destructive tort liability because a judge or lay jury concludes after the fact that both the manufacturer and the government were negligent in interpreting the results of such a test is a highly complex one. The government argues that its ability to make sound scientific and policy judgments would be impaired by exposure to tort liability. Lederle has similarly suggested that, if it is to continue participating in this crucial public health program, it must be able to rely on the government's judgments without fear that judges and juries in tort cases will reach different conclusions. There is no reason, on this record, for the Court to address that issue now, but neither should the Court complicate or prejudice its ultimate conclusions on that issue by adopting broad suggestions of a manufacturer's sole responsibility for regulatory compliance.

II. AN OVERLY BROAD IMPLICATION OF POTENTIAL TORT LIABILITY FOR VACCINE MANUFACTURERS WOULD UNDERMINE THE GOALS OF THE GOVERNMENT'S NATIONAL IMMUNIZATION POLICY.

The United States is in the midst of an unprecedented explosion of vaccine liability litigation. Hundreds of suits are pending, with damage claims totaling several billions

of dollars,[2] or about ten times the annual sales of the entire vaccine industry.[3] Many manufacturers have ceased making childhood vaccines because of their exposure to tort liability and their inability to obtain affordable liability insurance.[4]

The case at bar involves a heated scientific controversy over the live-cell Sabin oral polio vaccine, which the government's own authorities have selected as the polio vaccine of choice over the killed-cell Salk vaccine.[5] Some of the other pending cases are similar, and still others involve a related controversy about the vaccine selected by the government for immunization against diptheria, pertussis (whooping cough) and tetanus—the so-called DTP vaccine.

The pending DTP cases do not assert claims of government negligence in the licensure of the whole-cell DTP vaccine or in the approval of lots submitted for government testing. In many of these DTP suits, plaintiffs have asserted claims that a "design defect" requires imposition of liability on the vaccine manufacturer. The gist of these claims is that the defendant vaccine manufacturers (of which Lederle Laboratories is one) should have designed a different and less dangerous *type* of DTP

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[2] *Childhood Immunizations*, 99th Cong., 2d Sess. (Comm. Print 1986) at 85-86.

[3] Institute of Medicine, *Vaccine Supply and Innovation* (1985).

[4] H.R. Rep. No. 99-908, 99th Cong., 2d Sess. (1986), Part 1, at 6-7. Wyeth Laboratories recently ceased supplying the diptheria, pertussis, tetanus vaccine, leaving only two domestic suppliers. Lederle is the sole supplier of the oral polio vaccine, and Merck Sharp & Dohme is the sole supplier of the measles, mumps, rebella vaccine.

[5] *See also Johnson v. American Cyanamid Co.*, 718 P.2d 1318, 1322 (Kan. 1986) (holding as a matter of law that there is no design defect in Lederle's Sabin live-cell oral polio vaccine because the Sabin-type of vaccine utilized by Lederele "was the vaccine of choice recommended by all major health organizations in the United States.").

vaccine than the type *selected and approved* by the federal government, even though the government itself maintains that the different type has not yet been shown to be safe and effective for use.[6] Lay juries are invited, in effect, to make a *de novo* determination of which theoretically available vaccine should have been developed by the manufacturer. The question whether federal law has a pre-emptive effect that would bar such *de novo* determinations is in fact now pending in two Courts of Appeals.[7]

"Vaccination of children against deadly, disabling, but preventable infectious diseases has been one of the most spectacularly effective public health initiatives this country has ever undertaken." H.R. Rep. No. 99-908, 99th Cong., 2d Sess. (1986), Part 1, at 4. It is indeed true, as the government asserts, that the imposition of tort liability on the government in suits such as *Berkovitz* poses a serious threat to the continuance of these spectacularly effective programs. *See* Brief for the United States in Support of Petition for Certiorari at 8, *Berkovitz v. United States*, No. 87-498 (Dec. 1987). A decision by a lay jury that the government negligently licensed the only vaccine available to prevent a deadly childhood disease could leave the nation without any way of protecting its children. Too broad an imposition of tort liability against vaccine manufacturers could have an equally devastating effect. Any implication of sole and

[6] Brief of United States as Amicus Curiae, *Abbot v. American Cyanamid Co.*, No. 87-1578 (4th Cir.) (pending) ("based on their evaluation of the available scientific and medical evidence, HHS's public health experts have concluded that alternative pertussis vaccines have not yet been adequately shown to be safe and effective for licensure in the United States.").

[7] *Abbot v. American Cyanamid Co.*, No. 87-1578 (4th Cir.) (pending), *reviewing* No. 86-857-A (E.D. Va. March 9, 1987) (finding preemption); *Hurley v. Lederle Laboratories*, No. 87-2578 (5th Cir.) (pending), *reviewing* 651 F. Supp. 993 (E.D. Tex. 1986) (finding preemption).

potentially unlimited responsibility on the part of vaccine manufacturers who follow the government's lead or rely on the government's subjective interpretations of its own regulatory requirements could undermine or destroy these life-saving programs.

CONCLUSION

In *Berkovitz* the Court is called upon to decide only whether the discretionary function doctrine protects the federal government from exposure to tort liability for the alleged negligence of its employees in failing to follow its own regulatory guidelines. We submit that in making this determination, the Court should not intimate or infer that liability in such circumstances rests on the vaccine manufacturer.

Respectfully submitted,

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